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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/608,660      | 06/27/2003  | Karla Weaver         | 10123/00201         | 6994             |

7590

08/25/2005

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EXAMINER

DEAK, LESLIE R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3761     |              |

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/608,660             | WEAVER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Leslie R. Deak         | 3761                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/6/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,524,805 to Hoffman. Hoffman discloses an elastomeric valve 10 with valve body 12, lips 20, 22, and a slit. The lips are flexible and allow fluid to flow past the lips in an open position, and are held closed by the resilience of biasing lip margins 24, 26 that surround the lips and the slit (see column 4, lines 18-50). The lip margins may be rectangular (see FIG 8).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,524,805 to Hoffman in view of US 6,621,557 to Cushman et al. Hoffman fails to disclose a wire around the slit as a biasing member and that the valve is disk-shaped. Cushman discloses a disk-shaped resilient slit valve with wire 46 and shoulder end of

the bore 38 holding the valve in place and restraining the resilient material in a closed position. Therefore, it would have been ordinary to one having ordinary skill in the art at the time of invention to add a wire or resilient element around the slit of the valve disclosed by Hoffman in order to restrain the resilient material, maintaining a closed valve, as taught by Cushman.

5. Claims 9-11, 15-18, 22-24, 26, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,524,805 to Hoffman in view of US 5,810,789 to Powers.

Hoffman discloses the apparatus as claimed with the exception of a housing comprising a dual-lumen catheter and providing two flexible members, a third moveable element, and a second biasing member. Powers discloses a dual-lumen catheter with slit valves associated with each lumen of the catheter, thereby providing separate valving and fluid flow operation for each lumen. Providing additional flexible members, moveable elements, and biasing members is simply duplicating the single-lumen valve in the Hoffman device. It would have been obvious to one having ordinary skill in the art at the time of the invention to duplicate the moveable, resilient, and flexible members of the Hoffman device to provide independent valving operations for the dual lumens of the Powers catheter, since it has been held that the duplication of the essential working parts of a device involves only routine skill in the art. See MPEP 2144.04. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. Furthermore, applicant's recitation of silicone as a preferred material for the valve would have been obvious to one having ordinary skill in the art at the time of invention, since it has been held to be

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within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended purpose as a matter of obvious design choice. See MPEP 2144.07.

6. Claims 19-21, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,524,805 to Hoffman in view of US 6,621,557 to Cushman et al, further in view of US 5,810,789 to Powers. Hoffman fails to disclose a wire around the slit as a biasing member and that the valve is disk-shaped. Cushman discloses a disk-shaped resilient slit valve with wire 46 and shoulder end of the bore 38 holding the valve in place and restraining the resilient material in a closed position. Therefore, it would have been ordinary to one having ordinary skill in the art at the time of invention to add a wire or resilient element around the slit of the valve disclosed by Hoffman in order to restrain the resilient material, maintaining a closed valve, as taught by Cushman. Powers discloses a dual-lumen catheter with slit valves associated with each lumen of the catheter, thereby providing separate valving and fluid flow operation for each lumen. Providing additional flexible members, moveable elements, and biasing members is simply duplicating the single-lumen valve in the Hoffman device. It would have been obvious to one having ordinary skill in the art at the time of the invention to duplicate the moveable, resilient, and flexible members of the Hoffman device to provide independent valving operations for the dual lumens of the Powers catheter, since it has been held that the duplication of the essential working parts of a device involves only routine skill in the art. With regard to the plurality of wire segments, it has been held that constructing a formerly integral structure in various elements involves only routine skill

in the art. See MPEP 2144.04. With regard to the arrangement of the slits, It would have been an obvious manner of design choice to arrange the slits in various patterns, since applicant has not disclosed that the particularly claimed arrangement solves any stated problem or is for any particular purpose, and it appears that the invention would perform equally well with any arrangement of slits.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US 5,707,357 Mikhail et al
  - i. Catheter with varied arrangement of slits for valve
- b. US 2004/0186444 Daly et al
  - ii. Slit valves with dual lumen catheter housing
- c. US 2005/0043703 Nordgren
  - iii. Slit valves for dual lumen catheters

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd

18 August 2005

**TATYANA ZALUKAEVA**  
**PRIMARY EXAMINER**

